**[TITLE OF STUDY]**

**Principal Investigator Co-Investigators**

1. **Introduction**
2. **Hypothesis**
3. **Objective**
4. **Methodology**
5. **Study site**
6. **Design**

**Outcome Measures**

**Study subjects’ recruitment process**

***Study populations***

1. *Inclusion criteria*
2. *Sample size determination and sampling procedures*

**Study time frame**

**Resource requirements**

**Data Management**

1. *Type of data to be collected*
2. *Data storage and security*
3. *Data analysis*
4. **Ethical Consideration**
5. *Individual informed consent processes*

1. *Risks to the study subjects*
2. *Direct/indirect benefits and costs of the study*
3. *Dissemination of information or findings*
4. **Expected Application of the Results**

**References**